IS 5347-1 (1986): Requirements for Orthopedic Implants, Part 1: General Requirements [MHD 2: Orthopaedic Instruments, Implants and Accessories]

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IS : 5347 ( Part 1 ) - 1986
( Reaffirmed 2002 )

# *Indian Standard*

# REQUIREMENTS FOR ORTHOPAEDIC IMPLANTS

## PART 1 GENERAL REQUIREMENTS

## *( Second Revision )*

UDC 615·465 : 616·71-089·843



INDIAN STANDARDS INSTITUTION
MANAK BHAVAN, 9 BAHADUR SHAH ZAFAR MARG
NEW DELHI 110002

Gr 2

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# *Indian Standard*

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## 0. FOREWORD

**0.1** This Indian Standard ( Second Revision ) was adopted by the Indian Standards Institution on 24 January 1986, after the draft finalized by the Orthopaedic Instruments and Accessories Sectional Committee had been approved by the Consumer Products and Medical Instruments Division Council.

**0.2** In this specification an attempt has been made to deal with such requirements of surgical implants which are common in many of the implants used in bone surgery. The materials specified, in the light of present knowledge, provide optimum mechanical properties in relation to requirements for corrosion resistance and physical compatibility with living tissues. All metals will corrode or erode in the body to a greater or a lesser extent depending on the local conditions.

**0.3** In the case of implants made of any metal, it is of importance to ensure that the components are made of materials of the same composition in order to reduce the incidence of electrolytic corrosion. The screws used with the bone plates should, therefore, have the same composition of the material as that for the bone plates.

**0.4** In determining the choice of material to be used in any particular case, due regard should be paid to its mechanical properties, for example, unalloyed titanium is unsuitable for load bearing surface that involve movement of metal to metal.

**0.5** This Indian Standard adopts the material requirements of the ISO standards as given below:

ISO 5832/1 Implants for surgery — Metallic materials — Part 1 : Wrought stainless steel

ISO 5832/2 Implants for surgery — Metallic materials — Part 2 : Unalloyed titanium

ISO 5832/3 Implants for surgery — Metallic materials — Part 3 : Wrought titanium 6 — aluminium 4-vanadium alloy

ISO 5832/4 Implants for surgery — Metallic materials — Part 4 : Cobalt-chromium-molybdenum casting alloy

ISO 5832/5 Implants for surgery — Metallic materials — Part 5 : Wrought cobalt-chromium-tungsten-nickel alloy

ISO 5832/6 Implants for surgery — Metallic materials — Part 6 : Wrought cobalt-nickel-chromium-molybdenum alloy

ISO 5832/7 Implants for surgery — Metallic materials — Part 7 : Forgeable and cold-formed cobalt-chromium-nickel-molybdenum-iron alloy

ISO 6474 Implants for surgery-ceramic materials based on alumina

**0.6** For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test or analysis, shall be rounded off in accordance with IS : 2-1960*. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

## 1. SCOPE

**1.1** This standard specifies general requirements for surgical implants used for bone surgery.

## 2. TERMINOLOGY

**2.0** For the purpose of this standard, the following definition shall apply.

**2.1 Metal Surgical Implants** — The metal inserts which are used in surgery as implant and may be left temporarily or permanently inside the body.

*Rules for rounding off numerical values ( *revised* ).

## 3. MATERIALS

**3.1** The following materials shall be employed for the manufacture of implants either individually or in combination:

a) Wrought stainless steel according to IS : 5347 ( Part 2 )-1984*.

b) Unalloyed titanium according to IS : 5347 ( Part 3 )-1984*.

c) Wrought titanium 6-aluminium 4-vanadium alloy according to IS : 5347 ( Part 4 )-1984*.

d) Cobalt-chromium-molybdenum casting alloy according to IS : 5347 ( Part 5 )-1984*.

e) Wrought cobalt-chromium-tungsten-nickel alloy according to IS : 5347 ( Part 6 )-1984*.

f) Wrought cobalt-nickel-chromium-molybdenum alloy according to IS : 5347 ( Part 7 )-1984*.

g) Forgeable and cold-formed cobalt-chromium-nickel-molybdenum-iron alloy according to IS : 5347 ( Part 8 )-1984*.

h) Ceramic materials based on alumina according to IS : 5347 ( Part 9 )-1984*.

## 4. MANUFACTURE, WORKMANSHIP AND FINISH

**4.1** All implants shall be free from cracks, drawmarks, pits, burrs, surface contamination and impregnated foreign particles. The implants shall be electropolished and passivated to give a bright or satin finish.

## 5. TESTS

**5.1 Corrosion Resistance Tests** — The implants shall be tested for corrosion resistance as prescribed in **5.1.1**.

**5.1.1 Copper Sulphate Test for Corrosion Resistance** — The sample shall be scrubbed with soap and warm water, rinsed in hot water, followed by a dip in ethyl alcohol ( 95 percent ) and dried. The sample shall be completely immersed in copper sulphate solution at room temperature for 6 minutes and shall then be washed off

*Requirements for orthopaedic implants:
Part 2 Wrought stainless steel
Part 3 Unalloyed titanium
Part 4 Wrought titanium 6-aluminium 4-vanadium alloy
Part 5 Cobalt-chromium-molybdenum casting alloy
Part 6 Wrought cobalt-chromium-tungsten-nickel alloy
Part 7 Wrought cobalt-nickel-chromium-molybdenum alloy
Part 8 Forgeable and cold-formed cobalt-chromium-nickel-molybdenum-iron alloy
Part 9 Ceramic materials based on alumina

with fresh water or wet cotton wool. The copper sulphate solution shall be made up as follows:

| | |
|---|---|
| Copper sulphate ( $CuSO_4 \cdot 5H_2O$ ) | 4·0 g |
| Sulphuric acid ( $H_2SO_4$ ) ( relative density 1·84 ) ( *see* IS : 266-1977* ) | 10·0 g |
| Water ( *see* IS : 1070-1977† ) | 90·0 g |

There shall be no red stains or spots on the sample after the test, but the polished surface getting dull shall be permitted.

## 6. MARKING

**6.1** Each implant shall be clearly and indelibly marked at a site of minimum stress by either an electric spark or by electrolytic etching method involving the removal of surface material, with the following information:

a) Name or trade-mark of the manufacturer;

b) Designation of the material, indicated by the number of the relevant standard for the material, or by use of a symbol when specified in relevant standard;

c) Size; and

d) Recorded code or symbol.

**6.1.1** The implants or the packets which contain the implants may also be marked with the ISI Certification Mark.

NOTE — The use of the ISI Certification Mark is governed by the provisions of the Indian Standards Institution ( Certification Marks ) Act and the Rules and Regulations made thereunder. The ISI Mark on products covered by an Indian Standard conveys the assurance that they have been produced to comply with the requirements of that standard under a well-defined system of inspection, testing and quality control which is devised and supervised by ISI and operated by the producer. ISI marked products are also continuously checked by ISI for conformity to that standard as a further safeguard. Details of conditions under which a licence for the use of the ISI Certification Mark may be granted to manufacturers or processors, may be obtained from the Indian Standards Institution.

## 7. PACKING

**7.1** The implants shall be packed as agreed to between the purchaser and the supplier, however, it is recommended that these may be packed in polyethylene bags or in wax-paper and then packed in cartons.

*Specification for sulphuric acid ( *second revision* ).

†Specification for water for general laboratory use ( *second revision* ).

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